

Rep. Joseph R. Pitts
Opening Statement
Energy and Commerce Subcommittee on Health
Hearing on “21st Century Cures: Examining the Role of Incentives in Advancing
Treatments and Cures for Patients”
June 11, 2014

The Subcommittee will come to order.

The Chair will recognize himself for an opening statement.

Today’s hearing provides us with an opportunity to examine an important aspect of the 21st Century Cures Initiative: whether current economic and regulatory incentives are sufficient to encourage robust investment in the research and development of innovative new drugs and medical technologies.

I am particularly interested in better understanding what we can do to make it more attractive for companies and venture capitalists to invest in the development of therapies that would provide hope to patients without adequate treatment options. After all, as we have learned, there are only effective treatments for 500 of the 7,000 known diseases impacting patients today.

To help close this innovation gap, as part of 21st Century Cures Initiative, we must take a fresh look at the challenges facing innovative companies and make certain the right incentives are in place so America is home to the next generation of cures.

The Hatch-Waxman Act created the modern generic drug industry as we know it and has brought great benefits to our nation’s patients and health care system. Nonetheless, as Senator Hatch recently explained, since the early 1980s, “the cost of developing a drug

has doubled, as has the number of clinical trials necessary to file a new drug application. [Further,] [t]he number of participants required for those trials has tripled.”

We continue to hear about the many unique challenges of developing and testing therapies for patients with rare diseases and certain types of cancer. However, we cannot lose sight of the fact that new products targeting diseases that impact large patient populations such as diabetes and Alzheimer’s take much longer to get to market and are therefore becoming less attractive for investors and companies to pursue. Innovative trial designs with surrogate endpoints are almost unheard of in some of these areas, despite the fact that patients and our health care system would greatly benefit from new treatments. If and when they ultimately get to the market, these products are often left with the *least* amount of patent life and are granted the *shortest* exclusivity periods. We must reexamine the incentive structure—particularly for small-molecule drugs—before we are left wondering who will be developing the next generation of treatments, and in which country.

Finally, for a variety of what are oftentimes different reasons, investment in new medical technology companies is at startlingly low levels. There are only 11 venture capital firms remaining in this space—down from almost 40 in 2007. In 2013, we witnessed the lowest level of initial funding activity in more than two decades. This is not only a cures issue; this is a jobs issue and one we must address head on.

I want to welcome our witnesses today and look forward to learning more about the incentives necessary to encourage vital investment in biomedical innovation across the board.

Thank you, and I yield the remainder of my time to _____.